

shall bear, in addition to other information required by the law, the following statement conspicuously displayed:

Do not use in the area of the eye.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[65 FR 48377, Aug. 8, 2000; 65 FR 75158, Dec. 1, 2000]

### Subpart D—Medical Devices

#### § 73.3100 1,4-Bis[(2-hydroxyethyl)amino]-9,10-anthracenedione bis(2-propenoic)ester copolymers.

(a) *Identity.* The color additives are 1,4-bis[(2-hydroxyethyl)amino]-9,10-anthracenedione bis(2-propenoic)ester (CAS Reg. No. 109561-07-1) copolymerized either with glyceryl methacrylate, methyl methacrylate, and ethylene glycol dimethacrylate monomers, or with *N,N*-dimethyl acrylamide, methyl methacrylate, and ethylene glycol dimethacrylate monomers to form the contact lens material.

(b) *Uses and restrictions.* (1) The substances listed in paragraph (a) of this section may be used in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization and compliance with these uses shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) with respect to the contact lens made from the color additives.

(c) *Labeling.* The label of the color additives shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of these color additives is not necessary for the protection of the public health and therefore the color additives are exempt from the certification requirements of section 721(c) of the act.

[61 FR 51586, Oct. 3, 1996]

#### § 73.3105 1,4-Bis[(2-methylphenyl)amino]-9,10-anthracenedione.

(a) *Identity.* The color additive is 1,4-bis[(2-methylphenyl)amino]-9,10-anthracenedione (CAS Reg. No. 6737-68-4).

(b) *Uses and restrictions.* (1) The substance listed in paragraph (a) of this section may be used as a color additive in contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization and compliance with this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act (the act). A person intending to introduce a device containing 1,4-bis[(2-methylphenyl)amino]-9,10-anthracenedione listed under this section into commerce shall submit to the Food and Drug Administration either a premarket notification in accordance with subpart E of part 807 of this chapter, if the device is not subject to premarket approval, or submit and receive approval of an original or supplemental premarket approval application if the device is subject to premarket approval.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification requirements of section 721(c) of the act.

[49 FR 30066, July 26, 1984]

#### § 73.3106 1,4-Bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone copolymers.

(a) *Identity.* The color additive is 1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone (CAS Reg. No. 121888-69-5), copolymerized with hydroxyethyl methacrylate monomer, or a blend of hydroxyethyl methacrylate and *N*-vinyl pyrrolidone monomers, or a blend of 3-[tris(trimethylsiloxy)silyl]propyl vinyl

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carbamate (CAS Reg. No. 134072-99-4) and *N*-vinyl pyrrolidone monomers to form the contact lens material.

(b) *Uses and restrictions.* (1) The substances listed in paragraph (a) of this section may be used in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization and compliance with these uses shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) with respect to contact lenses made from the color additives.

(c) *Labeling.* The label of the color additives shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of these color additives is not necessary for the protection of the public health and, therefore, the color additives are exempt from the certification requirements of section 721(c) of the act.

[58 FR 17507, Apr. 5, 1993, as amended at 60 FR 10497, Feb. 27, 1995]

### § 73.3107 Carbazole violet.

(a) *Identity.* The color additive is carbazole violet (Pigment Violet 23) (CAS Reg. No. 6358-30-1, Colour Index No. 51319).

(b) *Uses and restrictions.* (1) The substance listed in paragraph (a) of this section may be used as a color additive in contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization for this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) with respect to the contact lens in which the color additive is used.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification

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requirements of section 721(c) of the act.

[53 FR 41324, Oct. 21, 1988]

### § 73.3110 Chlorophyllin-copper complex, oil soluble.

(a) *Identity.* The color additive is chlorophyllin-copper complex, oil soluble. The chlorophyllin is obtained by extraction from a mixture of fescue and rye grasses. The chlorophyll is acid-treated to remove chelated magnesium which is replaced with hydrogen, which is then replaced with copper. This mixture is diluted to a 5 percent concentration with a mixture of palm oil, peanut oil, and hydrogenated peanut oil.

(b) *Specifications.* The color additive chlorophyllin-copper complex, oil soluble (5 percent in palm oil, peanut oil, and hydrogenated peanut oil), shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by current good manufacturing practice:

Moisture, not more than 0.5 percent.

Nitrogen, not less than 0.2 percent and not more than 0.3 percent.

Total copper, not less than 0.2 percent and not more than 0.4 percent.

Free copper, not more than 200 parts per million.

Lead, not more than 20 parts per million.

Arsenic, not more than 5 parts per million.

Sulfated ash, not more than 2.5 percent.

Total color, not less than 4.5 percent and not more than 5.5 percent.

(c) *Uses and restrictions.* (1) The color additive chlorophyllin-copper complex, oil soluble (5 percent in palm oil, peanut oil, and hydrogenated peanut oil), may be safely used to color polymethylmethacrylate bone cement. Chlorophyllin-copper complex may be used at levels that do not exceed 0.003 percent by weight of the bone cement.

(2) Authorization for this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the polymethylmethacrylate bone cement in which chlorophyllin-copper complex, oil soluble, is used.